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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHRISTOPHER LEAGRE, Derivatively on Behalf of JOHNSON & JOHNSON, Plaintiff, v. ALEX GORSKY, JENNIFER L. TAUBERT, JOAQUIN DUATO, ANNE M. MULCAHY, CHARLES PRINCE, WILLIAM D. PEREZ, IAN E. L. DAVIS, RONALD A. WILLIAMS, A. EUGENE WASHINGTON, MARK B. MCCLELLAN, D. SCOTT DAVIS, MARY C. BECKERLE, MARY S. COLEMAN, JAMES G. CULLEN, LEO F. MULLIN, MICHAEL M. E. JOHNS, and DAVID SATCHER, Defendants, -and- JOHNSON & JOHNSON, a New Jersey corporation, Nominal Defendant.	)	Case No. VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT FOR BREACH OF FIDUCIARY DUTY AND UNJUST ENRICHMENT <u>DEMAND FOR JURY TRIAL</u>

Plaintiff Christopher Leagre, located at 12851 Norfolk Circle, Carmel, Indiana, by his attorneys, submits this Verified Stockholder Derivative Complaint for Breach of Fiduciary Duty and Unjust Enrichment. Plaintiff alleges the following on information and belief, except as to the allegations specifically pertaining to plaintiff which are based on personal knowledge. This complaint is also based on the investigation of plaintiff's counsel, which included, among other things, a review of public filings with the U.S. Securities and Exchange Commission ("SEC") and a review of news reports, press releases, and other publicly available sources.

NATURE AND SUMMARY OF THE ACTION

1. This is a stockholder derivative action brought by plaintiff on behalf of nominal defendant Johnson & Johnson ("J&J" or the "Company") against certain of its officers and directors for breach of fiduciary duty, unjust enrichment, and violations of law. These wrongs resulted in billions of dollars in damages to J&J's reputation, goodwill, and standing in the business community. Moreover, these actions have exposed J&J to billions of dollars in potential liability for violations of law.

2. J&J and its subsidiaries manufacture, sell, and distribute a range of medical devices and pharmaceutical drugs, including opioids. Opioids are categorized as "Schedule II Controlled Substances" due to their high potential for abuse and potential to cause severe psychological or physiological dependence. Given these risks, generally accepted standards of medical practice historically dictated that opioids be used only short-term, for instance, for acute pain, pain relating to recovery from surgery, or cancer or palliative care. In those instances, the risk of addiction is low or of little significance.

3. Beginning in the mid-1990s, J&J and other opioid developers (collectively, the "Opioid Manufacturers")[1] set out to enlarge the narrow opioid patient profile by reversing the traditional understanding of opioid use. To convince medical professionals to prescribe more opioids to a broader range of patients, the Opioid Manufacturers executed massive and unprecedented marketing campaigns that minimized the risks and exaggerated the benefits associated with the long-term use of opioids to treat wide-ranging conditions, including chronic noncancer pain. The Opioid Manufacturers: (i) deceptively promised long-term opioid use would improve patients' function and quality of life; (ii) trivialized or obscured the serious risks and adverse outcomes, including the risk of addiction, overdose, and death, associated with opioid use; (iii) overstated the effectiveness of opioids compared with other treatments; and (iv) mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms. The Opioid Manufacturers also deceptively marketed opioids for indications and benefits that were outside of the drugs' labels.

4. The Opioid Manufacturers' marketing and promotional efforts included, among other things, disseminating favorable "educational" materials, advertising in print materials and online, sponsoring continuing medical education courses, and hiring "key opinion leaders" to act as consultants and serve as lecturers. These efforts were intended to increase the market for opioids by influencing the prescribing behavior of physicians and convincing doctors to prescribe opioids for chronic noncancer pain.

5. The Opioid Manufacturers' deceptive marketing schemes were overwhelmingly successful, resulting in a dramatic shift in the medical and public consensus regarding the use of

[1] The "Opioid Manufacturers" refers to the following companies, collectively: J&J, Purdue, Actavis, Endo, Cephalon, Mallinckrodt, KVK-Tech, and Amneal.

opioids. Between 1999 and 2010, sales of prescription opioids in the U.S. quadrupled. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers—enough to medicate every adult in America around the clock for one month. Opioids—once a niche drug—are now the most prescribed class of drugs in the U.S.

6. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has been catastrophic, causing a substantial rise in opioid overdose deaths and opioid addiction treatment admissions. Nationally, from 1999 through 2016, more than 350,000 people in the U.S. died from an overdose involving opioids. Over 200,000 of those deaths involved patients who were prescribed opioids to treat pain. In 2017, more than 70,000 people died of drug overdoses, approximately two-thirds of those deaths were linked to opioids. According to the Centers for Disease Control and Prevention (the "CDC"), opioids have created a "public health epidemic."[2]

7. J&J played an integral role in fueling the opioid epidemic. The Company, through its subsidiary, Janssen Pharmaceuticals, Inc. ("Janssen"), aggressively and deceptively marketed the prescription opioids DURAGESIC®, NUCYNTA®, and NUCYNTA® ER for the long-term treatment of chronic pain. While these highly addictive narcotics have a potential for abuse similar to OxyContin and other Schedule II opioids, the Company marketed these products as "unlike traditional opioids" and as having "non-opioid" properties. J&J boasted that NUCYNTA and NUCYNTA ER were safer, milder, and less addictive than competitor products, like OxyContin.

8. The Company was well aware that these representations were false, deceptive, and unsupported by scientific evidence. In fact, the Company's own scientific advisors warned J&J

[2] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), https://www.cdc.gov/washington/testimony/2014/t20140429.htm.

that many of the marketing messages it used to promote opioids generally, as well as its own products, were misleading and should not be disseminated. The U.S. Food and Drug Administration ("FDA") also warned J&J that its marketing messages about opioids were misleading. In particular, in 2004, the FDA notified J&J that its marketing of DURAGESIC, a transdermal patch made out of the active pharmaceutical ingredient ("API") fentanyl, was deceptive and contained misleading and unsubstantiated claims about the effectiveness of the product and its potential for abuse. Yet, the Company continued to disseminate misleading messages about its products and opioids generally.

9. J&J further fueled the opioid epidemic by supplying other opioid manufacturers with APIs to be used in opioid drugs. From the 1990s through at least 2016, J&J, through its wholly owned subsidiaries Tasmanian Alkaloids Pty, Ltd. ("Tasmanian Alkaloids") and Noramco, Inc. ("Noramco"), supplied opioid APIs, including oxycodone, hydrocodone, morphine, codeine, and fentanyl, to other opioid manufacturers in the U.S. to be used in opioid drugs. By 2015, the Company's "Noramco World Wide Narcotics Franchise," comprised of Noramco and Tasmanian Alkaloids, was the number one supplier of narcotic APIs in the U.S. As a result, Janssen profited from the growth of both unbranded and branded opioids and was driven to develop the market as much as possible.

10. J&J's role in the opioid epidemic has subjected it to numerous lawsuits and governmental investigations. Since 2014, J&J and Janssen have been named as defendants in more than 2,500 lawsuits brought by various state and local governments related to their marketing of opioids. Additionally, over 2,200 federal cases accusing J&J and others of unlawful marketing practices have been coordinated in a federal multidistrict litigation ("MDL") pending in the U.S.

District Court for the Northern District of Ohio.[3] The Company has also received subpoenas or requests for information related to opioid marketing practices from a number of state attorneys general. In September 2017, the Texas and Colorado Attorney General's Offices contacted J&J on behalf of approximately thirty-eight states regarding a multistate Attorney General investigation. In August 2019, the U.S. Attorney's Office for the Eastern District of New York issued J&J a grand jury subpoena seeking documents related to the Company's antidiversion policies and procedures and distribution of opioid medications. Most recently, in September 2019, the Company received subpoenas from the New York State Department of Financial Services as part of its inquiry into the effect of opioid prescriptions of New York health insurance premiums.

11. These lawsuits and investigations have exposed the Company to billions of dollars in liability and already cost it hundreds of millions of dollars in settlements and adverse judgments. Finding that J&J promulgated "false, misleading, and dangerous marketing campaigns" that "caused exponentially increasing rates of addiction, overdose deaths," and babies born exposed to opioids, in August 2019, an Oklahoma state judge ordered the Company to pay the state $465 million.[4] On October 1, 2019, J&J announced that it had agreed to pay $20.4 million to resolve similar lawsuits brought by two Ohio counties. In mid-October 2019, the Company reached an agreement in principle with four state attorneys general, pursuant to which J&J would pay ***$4 billion*** over two or three years to resolve lawsuits over its contribution to the opioid-crisis.

12. On April 18, 2019, pursuant to New Jersey law, plaintiff sent a letter to the J&J Board of Directors (the "Board") demanding that the Board investigate the foregoing facts and

[3] *In re: National Prescription Opiate Litigation*, MDL No. 2804 (N.D. Ohio).

[4] While Judge Thad Balkman originally ordered J&J to pay $572 million, in November 2019, he announced there was an arithmetic error in the original order and reduced the judgment.

claims arising from them, and commence litigation against the corporate fiduciaries responsible for damaging J&J (the "Demand"). In response, J&J's counsel Sidley Austin LLP ("Sidley Austin"), sent plaintiff's counsel a letter stating that Lowenstein Sandler LLP ("Lowenstein Sandler") was investigating the "underlying matters regarding the Company's opioid products that are addressed in [the Demand]." Although the Company's letter disclosed that Douglas Eakeley from Lowenstein Sandler was leading the investigation, it did not state who at J&J Mr. Eakeley was reporting to, nor whether the Board had established a committee to oversee the investigation. The letter provided little more detail concerning the investigation, beyond that it was "underway and is currently in the fact-gathering stage." Notably, the Company's letter did not delineate the scope of the investigation, nor the anticipated duration of the investigation. Neither did the Company's letter address whether the Board had secured tolling agreements from potential defendants, as plaintiff had explicitly demanded in the Demand.

13. Plaintiff's counsel's subsequent correspondence with counsel at Sidley Austin produced little more detail concerning the status of the investigation and the Board's involvement in the investigation. Nearly eight months—far longer than the ninety days provided by statute—have passed since plaintiff first made his Demand, yet the Board has not provided a substantive response to the Demand.

14. Given the Board's lengthy and inexcusable delay, plaintiff brings this action to timely address the wrongdoing discussed herein that harmed and continues to harm the Company.

JURISDICTION AND VENUE

15. Jurisdiction is conferred by 28 U.S.C. §1332. Complete diversity among the parties exists and the amount in controversy exceeds $75,000, exclusive of interests and costs.

16. This Court has jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business in and maintains operations in this District,

or is an individual who has sufficient minimum contacts with this District to render the exercise of jurisdiction by the District courts permissible under traditional notions of fair play and substantial justice.

17. Venue is proper in this Court in accordance with 28 U.S.C. §1391 because: (i) J&J maintains its principal place of business in this District; (ii) one or more of the defendants either resides in or maintains executive offices in this District; (iii) a substantial portion of the transactions and wrongs complained of herein, including the defendants' primary participation in the wrongful acts detailed herein, and aiding and abetting and conspiracy in violation of fiduciary duties owed to J&J, occurred in this District; and (iv) defendants have received substantial compensation in this District by doing business here and engaging in numerous activities that had an effect in this District.

THE PARTIES

Plaintiff

18. Plaintiff Christopher Leagre was a stockholder of J&J at the time of the wrongdoing complained of, has continuously been a stockholder since that time, and is a current J&J stockholder. Plaintiff is a citizen of Indiana.

Nominal Defendant

19. Nominal defendant J&J is a New Jersey corporation with principal executive offices located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Accordingly, J&J is a citizen of New Jersey. J&J is a holding company with more than 260 operating subsidiaries. Through its subsidiaries, the Company engages in the research and development, manufacture and sale of products in the health care field. As of December 30, 2018, J&J had approximately 135,100 employees worldwide.

Defendants

20. Defendant Alex Gorsky ("Gorsky") is J&J's Chairman of the Board and has been since December 2012; and Chief Executive Officer, Chairman of the Executive Committee, and a director and has been since April 2012. Defendant Gorsky was also J&J's Vice Chairman of the Executive Committee from January 2011 to April 2012; a Member of the Executive Committee from January 2009 to January 2011; Worldwide Chairman, Medical Devices and Diagnostics Group from September 2009 to January 2011; Worldwide Chairman, Surgical Care Group from January 2009 to September 2009; Company Group Chairman and Worldwide Franchise Chairman for Ethicon, Inc., a subsidiary of the Company, from 2008 to January 2009; and held other various positions of increasing responsibility at the Company and its subsidiaries from 1988 to 2004. Defendant Gorsky knowingly, recklessly, or with gross negligence caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Gorsky the following compensation as an executive:

Year	Salary	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Change in Pension Value and Non-Qualified Deferred Compensation Earnings	All Other Compensation	Total
2018	$1,642,308	$10,319,463	$4,305,594	$3,570,497	-	$259,710	$20,097,572
2017	$1,600,000	$12,354,361	$5,054,398	$3,598,382	$6,959,144	$236,279	$29,802,564
2016	$1,600,000	$10,608,901	$4,118,398	$4,652,556	$5,663,771	$228,094	$26,871,720
2015	$1,613,462	$10,693,427	$4,562,998	$4,009,536	$2,714,268	$202,175	$23,795,866
2014	$1,500,000	$9,467,380	$4,168,139	$5,018,779	$4,606,142	$228,866	$24,989,306
2013	$1,453,846	$5,988,975	$2,669,999	$4,867,361	$1,739,000	$191,779	$16,910,960
2012	$1,087,188	$2,790,229	$1,482,631	$3,407,287	$2,050,000	$159,774	$10,977,109
2011	$847,692	$673,222	$1,081,161	$2,836,003	$1,316,000	$82,782	$6,836,860

Defendant Gorsky is a citizen of Pennsylvania.

21. Defendant Jennifer L. Taubert ("Taubert") is J&J's Executive Vice President, Worldwide Chairman, Pharmaceuticals and a Member of the Executive Committee and has been since July 2018. Defendant Taubert was also J&J's Company Group Chairman, The Americas, Pharmaceuticals from 2015 to July 2018; Company Group Chairman, North America

Pharmaceuticals from 2012 to 2015; and has held other various positions of increasing responsibility at the Company and its subsidiaries since joining the Company in 2005 as Worldwide Vice President, Johnson & Johnson Pharmaceutical Services. Defendant Taubert knowingly, recklessly, or with gross negligence caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. Defendant Taubert is a citizen of New Jersey.

22. Defendant Joaquin Duato ("Duato") is J&J's Vice Chairman of the Executive Committee and has been since July 2018. Defendant Duato was also J&J's Executive Vice President, Worldwide Chairman, Pharmaceuticals and a Member of the Executive Committee from April 2016 to July 2018; Worldwide Chairman, Pharmaceuticals from 2011 to April 2016; Company Group Chairman, Pharmaceuticals from 2009 to 2011; and has held other various positions of increasing responsibility at the Company and its subsidiaries since joining the Company in 1989. Defendant Duato knowingly, recklessly, or with gross negligence caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Duato the following compensation as an executive:

Year	Salary	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Change in Pension Value and Non-Qualified Deferred Compensation Earnings	All Other Compensation	Total
2018	$934,046	$4,275,951	$1,892,999	$2,010,088	$79,000	$91,876	$9,283,960
2017	$897,254	$11,483,016	$1,650,003	$1,928,262	$3,329,047	$71,726	$19,359,308
2016	$875,000	$3,198,483	$1,260,002	$2,158,006	$2,535,760	$77,278	$10,104,529

Defendant Duato is a citizen of New Jersey.

23. Defendant Anne M. Mulcahy ("Mulcahy") is J&J's Lead Director and has been since December 2012 and a director and has been since October 2009. Defendant Mulcahy is a member of J&J's Audit Committee and has been since at least March 2013. Defendant Mulcahy

knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Mulcahy the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2018	$150,000	$184,940	$20,000	$354,940
2017	$145,000	$174,893	-	$319,893
2016	$140,000	$164,985	$20,000	$324,985
2015	$140,000	$154,899	$20,000	$314,899
2014	$140,000	$154,924	$20,000	$314,924
2013	$140,000	$144,989	-	$284,989
2012	$110,000	$144,913	-	$254,913
2011	$122,500	$99,974	-	$222,474
2010	$112,500	$99,942	-	$212,442
2009	$19,355	$60,640	-	$79,995

Defendant Mulcahy is a citizen of Connecticut.

24. Defendant Charles Prince ("Prince") is a J&J director and has been since February 2006. Defendant Prince is the Chair of J&J's Regulatory Compliance Committee and has been since at least March 2017. Defendant Prince knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Prince the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2018	$135,000	$184,940	$20,000	$339,940
2017	$130,000	$174,893	$20,000	$324,893
2016	$130,000	$164,985	$20,000	$314,985
2015	$130,000	$154,899	$20,000	$304,899
2014	$130,000	$154,924	-	$284,924
2013	$130,000	$144,989	$20,524	$295,513
2012	$130,000	$144,913	$20,000	$294,913
2011	$137,500	$99,974	$20,000	$257,474
2010	$125,000	$99,942	-	$224,942
2009	$120,000	$99,978	-	$219,978

Defendant Prince is a citizen of Florida.

25. Defendant William D. Perez ("Perez") is a J&J director and has been since June 2007. Defendant Perez is a member of J&J's Audit Committee and has been since at least March 2017, and was previously a member of the Public Policy Advisory Committee from at least March 2009 to at least March 2010. Defendant Perez knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Perez the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2018	$135,000	$184,940	$20,000	$339,940
2017	$130,000	$174,893	$20,000	$324,893
2016	$130,000	$164,985	$20,000	$314,985
2015	$130,000	$154,899	$20,000	$304,899
2014	$130,000	$154,924	-	$284,924
2013	$130,000	$144,989	$20,000	$294,989
2012	$130,000	$144,913	$20,000	$294,913
2011	$132,500	$99,974	$20,000	$252,474
2010	$120,000	$99,942	$20,000	$239,942
2009	$110,000	$99,978	$20,000	$229,978

Defendant Perez is a citizen of Florida.

26. Defendant Ian E. L. Davis ("I. Davis") is a J&J director and has been since July 2010. Defendant I. Davis is a member of J&J's Audit Committee and has been since at least March 2011, and a member of the Regulatory Compliance Committee and has been since at least March 2017. Defendant I. Davis was previously a member of J&J's Public Policy Advisory Committee from at least March 2011 to at least March 2012, and a member of the Science, Technology & Sustainability Committee from at least March 2013 to at least March 2016. Defendant I. Davis knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected

the Company to billions of dollars in liability. J&J paid defendant I. Davis the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	Total
2018	$115,000	$184,940	$299,940
2017	$110,000	$174,893	$284,893
2016	$110,000	$164,985	$274,985
2015	$110,000	$154,899	$264,899
2014	$110,000	$154,924	$264,924
2013	$110,000	$144,989	$254,989
2012	$110,000	$144,913	$254,913
2011	$120,000	$99,974	$219,974
2010	$55,000	$59,580	$114,580

Upon information and belief, defendant I. Davis is a citizen of the United Kingdom.

27. Defendant Ronald A. Williams ("Williams") is a J&J director and has been since June 2011. Defendant Williams was previously the Chair of J&J's Regulatory Compliance Committee in at least March 2016, a member of that committee from at least March 2013 to at least March 2016, and a member of the Public Policy Advisory Committee in at least March 2012. Defendant Williams knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Williams the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2018	$130,000	$174,893	$20,000	$324,893
2017	$130,000	$174,893	$20,000	$324,893
2016	$130,000	$164,985	$20,000	$314,985
2015	$125,003	$154,899	$20,000	$299,902
2014	$110,000	$154,924	$20,000	$284,924
2013	$110,000	$144,989	-	$254,989
2012	$110,000	$144,913	-	$254,913
2011	$60,000	$67,060	-	$127,060

Defendant Williams is a citizen of Florida.

28. Defendant A. Eugene Washington ("Washington") is a J&J director and has been since November 2012. Defendant Washington is a member of J&J's Science, Technology & Sustainability Committee and has been since at least March 2013, and was previously a member of the Regulatory Compliance Committee from at least March 2013 to March 2014. Defendant Washington knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Washington the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2018	$115,000	$184,940	$20,000	$319,940
2017	$110,000	$174,893	-	$284,893
2016	$110,000	$164,985	$20,000	$294,985
2015	$110,000	$154,899	$20,000	$284,899
2014	$110,000	$154,924	$2,000	$266,924
2013	$110,000	$144,989	$5,772	$260,761
2012	$9,167	-	-	$9,167

Defendant Washington is a citizen of North Carolina.

29. Defendant Mark B. McClellan ("McClellan") is a J&J director and has been since October 2013. Defendant McClellan is a member of J&J's Regulatory Compliance Committee and the Science, Technology & Sustainability Committee and has been since at least March 2014. Defendant McClellan knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant McClellan the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	Total
2018	$115,000	$184,940	$299,940
2017	$110,000	$174,893	$284,893
2016	$110,000	$164,985	$274,985

2015	$110,000	$154,899	$264,899
2014	$110,000	$154,924	$264,924
2013	$27,500	-	$27,500

Defendant McClellan is a citizen of North Carolina.

30. Defendant D. Scott Davis ("S. Davis") is a J&J director and has been since June 2014. Defendant S. Davis is the Chair of J&J's Audit Committee and has been since at least March 2016, and a member of that committee and has been since at least March 2015. Defendant S. Davis was previously a member of J&J's Regulatory Compliance Committee from at least March 2015 to at least March 2016. Defendant S. Davis knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant S. Davis the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	Total
2018	$140,000	$184,940	$324,940
2017	$135,000	$174,893	$309,893
2016	$135,000	$164,985	$299,985
2015	$128,750	$154,899	$283,649
2014	$58,366	-	$58,366

Upon information and belief, defendant S. Davis is a citizen of Georgia.

31. Defendant Mary C. Beckerle ("Beckerle") is a J&J director and has been since June 2015. Defendant Beckerle is the Chair of J&J's Science, Technology & Sustainability Committee and has been since at least March 2017, a member of that committee and has been since at least March 2016, and a member of the Regulatory Compliance Committee and has been since at least March 2017. Defendant Beckerle knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Beckerle the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2018	$135,000	$184,940	$20,000	$339,940
2017	$130,000	$174,893	$20,000	$324,893
2016	$111,667	$164,985	$17,800	$294,452
2015	$64,167	-	-	$64,167

Defendant Beckerle is a citizen of Utah.

32. Defendant Mary S. Coleman ("Coleman") was a J&J director from September 2003 to April 2016. Defendant Coleman was a member of J&J's Audit Committee and the Science, Technology & Sustainability Committee from at least March 2009 to at least March 2016. Defendant Coleman knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Coleman the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2016	$36,666	$164,985	$20,000	$221,651
2015	$110,000	$154,899	$20,000	$284,899
2014	$110,000	$154,924	$20,000	$284,924
2013	$110,000	$144,989	$20,710	$275,699
2012	$110,000	$144,913	$20,000	$274,913
2011	$120,000	$99,974	$19,998	$239,972
2010	$110,000	$99,942	$19,998	$229,940
2009	$110,000	$99,978	$20,000	$229,978

Defendant Coleman is a citizen of Michigan.

33. Defendant James G. Cullen ("Cullen") was a J&J director from September 1995 to April 2015. Defendant Cullen was the Chair of J&J's Audit Committee from at least March 2009 to at least March 2015. Defendant Cullen knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Cullen the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2015	$45,000	$154,899	-	$199,899
2014	$135,000	$154,924	-	$289,924
2013	$135,000	$144,989	$20,000	$299,989
2012	$165,000	$144,913	-	$309,913
2011	$155,000	$99,974	$20,000	$274,974
2010	$130,000	$99,942	-	$229,942
2009	$130,000	$99,978	-	$229,978

Defendant Cullen is a citizen of New Jersey.

34. Defendant Leo F. Mullin ("Mullin") was a J&J director from July 1999 to April 2015. Defendant Mullin was a member of J&J's Audit Committee from at least March 2009 to March 2015; the Chair of the Regulatory Compliance Committee from April 2012 to at least March 2015; and the Chair of the Public Policy Advisory Committee from at least March 2009 to April 2012. Defendant Mullin knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Mullin the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2015	$43,333	$154,899	$20,000	$218,232
2014	$130,000	$154,924	-	$284,924
2013	$130,000	$144,989	$21,884	$296,873
2012	$130,000	$144,913	$16,666	$291,579
2011	$130,000	$99,974	$20,000	$249,974
2010	$120,000	$99,942	$20,000	$239,942
2009	$120,000	$99,978	$20,000	$239,978

Defendant Mullin is a citizen of Georgia.

35. Defendant Michael M. E. Johns ("Johns") was a J&J director from April 2005 to April 2014. Defendant Johns was a member of J&J's Science, Technology & Sustainability Committee from at least March 2009 to at least March 2014. Defendant Johns knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading

marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Johns the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2014	$36,667	$154,924	$20,000	$211,591
2013	$110,000	$144,989	$10,000	$264,989
2012	$110,000	$144,913	$20,000	$274,913
2011	$122,500	$99,974	$10,000	$232,474
2010	$112,500	$99,942	$10,000	$222,442
2009	$110,000	$99,978	$20,000	$229,978

Defendant Johns is a citizen of Georgia.

36. Defendant David Satcher ("Satcher") was a J&J director from April 2002 to April 2013. Defendant Satcher was a member of J&J's Public Policy Advisory Committee from at least March 2009 to April 2012; a member of the Regulatory Compliance Committee from April 2012 to at least March 2013; the Chair of the Science, Technology & Sustainability Committee from at least March 2009 to March 2012, and a member of that committee until at least March 2013. Defendant Satcher knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Satcher the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2013	$36,667	$144,989	$22,247	$203,903
2012	$130,000	$144,913	$10,000	$284,913
2011	$130,000	$99,974	$20,000	$249,974
2010	$120,000	$99,942	$20,000	$239,942
2009	$120,000	$99,978	$20,000	$239,978

Defendant Satcher is a citizen of Georgia.

37. The defendants identified in ¶¶20-22 are referred to herein as the "Officer Defendants." The defendants identified in ¶¶20, 23-36 are referred to herein as the "Director Defendants." Collectively, the defendants identified in ¶¶20-36 are referred to herein as the "Individual Defendants."

DUTIES OF THE INDIVIDUAL DEFENDANTS

Fiduciary Duties

38. By reason of their positions as officers and directors of the Company, each of the Individual Defendants owed and owe J&J and its stockholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to control and manage J&J in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of J&J and not in furtherance of their personal interest or benefit.

39. To discharge their duties, the officers and directors of J&J were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the financial affairs of the Company. By virtue of such duties, the officers and directors of J&J were required to, among other things:

(a) ensure that the Company was operated in a diligent, honest, and prudent manner in compliance with all applicable laws, rules, and regulations;

(b) ensure that the Company complied with its legal obligations and requirements, and refrain from engaging in deceptive conduct;

(c) conduct the affairs of the Company in an efficient, business-like manner in compliance with all applicable laws, rules, and regulations so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock; and

(d) remain informed as to how J&J conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiry in connection therewith, and take steps to correct such conditions or practices and make such disclosures as necessary to comply with applicable laws.

J&J's Principles of Corporate Governance and Code of Business Conduct Impose Additional Responsibilities on the Defendants

40. The Individual Defendants, like all employees, directors, and officers of the Company, were required to comply with J&J's Principles of Corporate Governance (the "Corporate Governance Principles") and Code of Business Conduct (the "Code of Conduct"). The Individual Defendants were also required to comply with the Company's Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers (the "D&O Code of Conduct").[5] The Corporate Governance Principles state the following with respect to the responsibilities of the Board:

> **Responsibilities of the Board.** All Directors are elected annually by the shareholders as their representatives in providing oversight of the operation of the Company. The Directors select, oversee and monitor the performance of the senior management team, which is charged with the day-to-day conduct of the Company's business. The fundamental responsibility of the Directors is to exercise their business judgment on matters of critical and long-term significance to the Company in furtherance of what they reasonably believe to be in the best interest of the Company, and therefore its shareholders.

41. In addition to the duties described above, the Company vouched to conduct its business in accordance with applicable laws and regulations. To that effect, both the Code of Conduct and the D&O Code of Conduct required the Company's officers and directors to comply with all laws, rules, and regulations, and the D&O Code of Conduct further required the Individual

[5] The D&O Code of Conduct refers to the Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers updated March 7, 2016.

Defendants to "use all reasonable efforts to oversee compliance by employees, other Directors and other Executive Officers with all applicable laws, rules and regulations." The Code of Conduct provided the following with respect to legal and regulatory compliance:

> We aspire to bring the highest standards and level of integrity to each of these business activities by:
>
> - Complying with the laws, standards and regulations that apply to our products and processes (such as quality regulations and standards);
> - Upholding ethical, scientific and clinical standards and complying with all laws and regulations in all research and development activities worldwide;
> - Ensuring the safety of patients and volunteers who take part in clinical trials, protecting their confidentiality and complying with data protection laws;
> - Complying with the laws and regulations that cover gaining marketing authorization to sell our products and interacting with regulators and other government officials;
> - Adhering to the applicable manufacturing, packaging, distribution and export laws and regulations for our industry and in the countries where we do business;
> - ***Following all laws and regulations regarding the promotion, marketing and sales of our products,*** including ensuring that what we say is truthful, not misleading, and is consistent with regulatory approvals for our products;
> - Complying with all laws relating to product quality and safety, consistently monitoring the safety, quality and performance of our products and complying with all requirements for reporting adverse events and product quality complaints.

42. Thus, J&J's Principles of Corporate Governance and its Codes of Conduct made clear that the Individual Defendants were tasked with taking all necessary and appropriate steps to make sure that the Company, including its highest management, complied with all applicable internal policies and fair business practices.

Breaches of Duties

43. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as officers and directors of J&J, the absence of good

faith on their part, and a reckless disregard for their duties to the Company that the Individual Defendants were aware or reckless in not being aware posed a risk of serious injury to the Company.

44. The Individual Defendants breached their duty of loyalty and good faith by allowing defendants to cause, or by themselves causing, the Company to engage in deceptive practices with respect to its marketing and promotion of opioids. These improper practices caused J&J to incur substantial damage.

45. The Individual Defendants, because of their positions of control and authority as officers and/or directors of J&J, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein. The Individual Defendants also failed to prevent the other Individual Defendants from taking such illegal actions. As a result, and in addition to the damage the Company has already incurred, J&J has expended, and will continue to expend, significant sums of money.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

46. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their common plan or design. In addition to the wrongful conduct herein alleged as giving rise to primary liability, the Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

47. During all times relevant hereto, the Individual Defendants, collectively and individually, initiated a course of conduct that was designed to and did: (i) deceive the public as to the benefits of opioids and their associated risks; and (ii) enhance the Individual Defendants' executive and directorial positions at J&J and the profits, power, and prestige that the Individual Defendants enjoyed as a result of holding these positions. In furtherance of this plan, conspiracy,

and course of conduct, the Individual Defendants, collectively and individually, took the actions set forth herein.

48. The Individual Defendants engaged in a conspiracy, common enterprise, and/or common course of conduct. During this time, the Individual Defendants caused the Company to disseminate misleading information about the benefits and risks associated with opioids.

49. The purpose and effect of the Individual Defendants' conspiracy, common enterprise, and/or common course of conduct was, among other things, to disguise the Individual Defendants' violations of law, breaches of fiduciary duty, and unjust enrichment; and to conceal adverse information concerning the Company's operations and future business prospects.

50. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or common course of conduct complained of herein.

51. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each Individual Defendant acted with knowledge of the primary wrongdoing, substantially assisted in the accomplishment of that wrongdoing, and was aware of his or her overall contribution to and furtherance of the wrongdoing.

FACTUAL BACKGROUND

52. J&J and its subsidiaries manufacture, sell, and distribute a range of pharmaceutical drugs, including opioids. Among other opioid products, the Company promotes, distributes, and sells DURAGESIC, a transdermal patch made out of the API fentanyl, a synthetic opioid that is 100 times stronger than morphine and fifty times stronger than heroin. Prior to 2009, DURAGESIC accounted for at least $1 billion in annual sales. Until January 2015, the Company also developed, marketed, and sold NUCYNTA and NUCYNTA ER—tablets made out of the

API, tapentadol. Together, NUCYNTA and NUCYNTA ER accounted for $172 million in sales in 2014.

53. Opioids, including DURAGESIC, NUCYNTA, and NUCYNTA ER, are categorized as "Schedule II Controlled Substances" due to their high potential for abuse and potential to cause severe psychological and physiological dependence. Most patients receiving more than a few weeks of opioid therapy will experience withdrawal symptoms if opioid use is delayed or discontinued—including severe anxiety, nausea, headaches, tremors, delirium, and pain—which are often prolonged. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e., to relief of pain) and require progressively higher doses which increases the risks of withdrawal, addiction, and overdose.

54. Recognizing these dangers, historically the medical community prescribed opioids only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction was minimal—and for terminal illnesses and end-of-life care. As a result, the market for prescription opioids was sharply constrained. Not so today. Today, opioids are the most prescribed class of drugs in the U.S.

55. The roots of the opioid epidemic date back to the mid-1990s when Purdue developed the opioid OxyContin. In 1994, the same year Purdue sought approval from the FDA to sell OxyContin, J&J, through its subsidiary, Tasmanian Alkaloids, established a research project for the development of a high thebaine poppy to meet the anticipated demand for OxyContin. This project resulted in the development of the "Norman" poppy, which coincided with the release of a

slow release formulation of oxycodone in the U.S.[6] J&J internally described the new poppy as "a transformational technology." The Norman poppy enabled the growth of oxycodone.

56. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, a relatively weak oxycodone-acetaminophen combination pill. Oxycodone was sometimes mistakenly called "oxycodeine," which contributed to the perception of relatively lower potency, because codeine is weaker than morphine. Purdue took advantage of these misconceptions, marketing OxyContin as lower risk than traditional immediate release narcotics.[7]

57. Purdue sought to expand the market for OxyContin by changing prescribers' perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions like back pain, migraines, and arthritis. As part of its strategy, in addition to promoting its OxyContin product as lower-risk than traditional opioids, Purdue promoted opioids in general as safe, effective, and appropriate for long-term use for routine pain conditions, and misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use. Purdue spent tens of millions of dollars every year to support its promotional efforts. Purdue was successful in creating a market for the use of opioids for a range of common aches and pains.

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[6] A.J. Fist, *The Tasmanian Poppy Industry: A Case Study of the Application of Science and Technology*, Tasmanian Alkaloids Pty. Ltd., Westbury, Tasmania.

[7] Purdue acknowledged using this to its advantage when it later pled guilty to criminal charges of "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps ... that would affect the unique position that OxyContin'" held among physicians. Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, Esquire (Oct. 16, 2017), http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/.

THE COMPANY ENGAGED IN A DECEPTIVE MARKETING SCHEME TO UNLAWFULLY INCREASE ITS REVENUE FROM OPIOIDS

58. J&J and other opioid developers took advantage of the market created by Purdue's aggressive promotion of OxyContin by bringing new opioids to market and expanding the use of their existing opioid products. To develop the market, the Opioid Manufacturers engaged in widespread deceptive marketing campaigns designed to convince healthcare providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven. The result has been catastrophic. The United States is now awash in opioids. According to the CDC, the nation has been swept up in an opioid-induced "public health epidemic."

59. As detailed below, J&J played a major role in causing the opioid epidemic. J&J not only participated in this deceptive opioid promotion scheme, but through its subsidiaries Noramco and Tasmanian Alkaloids, the Company also supplied opium-based ingredients to other opioid manufacturers. Thus, J&J profited not only from sales of its own opioid products, but also from the sale of its API to other manufacturers and was driven to develop the market as much as possible.

The Opioid Manufacturers' Deceptive Opioid Promotion Scheme

60. The Opioid Manufacturers spent hundreds of millions of dollars on promotional activities and materials, including advertising and websites that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. In particular, the Opioid Manufacturers' deceptive marketing included: (i) misrepresenting that opioids improve function; (ii) concealing the link between long-term use of opioids and addiction; (iii) misrepresenting that addiction risk can be managed; (iv) masking the signs of addiction by calling them "pseudoaddiction"; (v) falsely claiming withdrawal is easily managed; (vi) misrepresenting or omitting the greater dangers from

higher doses of opioids; and (vii) minimizing the adverse effects of opioids and overstating the risks of nonsteroidal anti-inflammatory drugs ("NSAIDs").

61. ***First***, to convince medical professionals to prescribe more opioids to a broader range of patients, the Opioid Manufacturers touted the purported benefits of long-term opioid use, and claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs. These claims encouraged doctors to continue opioid therapy in the belief that failure to improve pain, function, or quality of life could be overcome by increasing doses or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.

62. The Opioid Manufacturers' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. According to the CDC's Guideline for Prescribing Opioids for Chronic Pain (the "CDC Guideline"), there is "insufficient evidence to determine long-term benefits of opioid therapy for chronic pain." In fact, the CDC has found that there is "[n]o evidence show[ing] a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)." The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[8]

63. Not only is there no evidence of improvement in long-term functioning, but the available evidence indicates that other treatments are more or equally effective and less harmful than long-term opioid use. For instance, a 2006 study-of-studies found that "[f]or functional

[8] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

outcomes ... other analgesics were significantly more effective than were opioids."[9] Studies of the use of opioids in chronic conditions for which they are now commonly prescribed corroborate this conclusion. These studies have consistently shown that patients using opioids long-term experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[10]

64. ***Second***, the Opioid Manufacturers sought to convince prescribers and patients that opioids are safe by misrepresenting the risk of addiction from chronic opioid therapy. The Opioid Manufacturers brazenly maintained that the risk of addiction for patients who take opioids long-term was low and omitted the risk of addiction and abuse from the list of adverse outcomes associated with chronic opioid use, even though the frequency and magnitude of the risk compelled disclosure. The Opioid Manufacturers also undermined evidence that opioids are addictive by representing that the risk of addiction is limited to high-risk patients. There was no scientific evidence to support those claims, and in fact, the available research contradicted them. A 2015

[9] Andrea D. Furlan, et al., *Opioids for Chronic Noncancer Pain: a Meta-Analysis of Effectiveness and Side Effects*, 174(11) Can. Med. Ass'n J. 1589-94 (2006). This study revealed that efficacy studies do not typically include data on opioid addiction, such that, if anything, the data overstate effectiveness.

[10] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009).

literature survey found that while ranges of "problematic use" of opioids ranged from 1% to 81%, abuse averaged between 21% and 29%, and addiction between 8% and 12%.[11]

65. In addition to making outright misrepresentations about the risk of opioid addiction generally, the Opioid Manufacturers falsely represented that their respective opioid drugs were safer, and less prone to abuse and addiction than other opioids. For instance, Actavis, Endo, Janssen, and Purdue each promoted their drugs as having "steady-state" properties—meaning that their drugs caused less of a rush or a feeling of euphoria, which can trigger abuse and addiction—and therefore were less likely to be abused or cause addiction.

66. ***Third***, to encourage physicians to prescribe more opioids, the Opioid Manufacturers repeatedly promoted the concept of "pseudoaddiction." The Opioid Manufacturers told prescribers that classic signs of addiction, such as asking for increasingly higher doses of opioids or seeking early refills, actually reflected undertreated pain that should be addressed with heavier doses of opioids. The Opioid Manufacturers' also promoted "pseudoaddiction" through unbranded promotional materials funneled through third parties. Their unbranded marketing campaigns frequently focused on heightening awareness of the undertreatment of pain and its consequences. Their marketing materials repeatedly represented that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be overregulated and underprescribed.

67. The Opioid Manufacturers' claims of "pseudoaddiction" were not substantiated by scientific evidence. In fact, the CDC Guideline for prescribing opioids for chronic pain rejects the concept of pseudoaddiction. To the contrary, the CDC Guideline explains that "[p]atients who do

[11] Kevin Vowels, et al., *Rates of Opioid Misuse, Abuse, and Addiction in Chronic Pain: a Systematic Review and Data Synthesis*, 156 PAIN 569-76 (April 2015).

not experience clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

68. ***Fourth***, the Opioid Manufacturers misrepresented that addiction risk can be avoided or managed. The Opioid Manufacturers told prescribers that to the extent there is a risk of opioid addiction, doctors can avoid or manage that risk by using screening tools and questionnaires. The Opioid Manufacturers advised doctors that they could use these tools to identify patients with higher addiction risks and closely monitor patients at greater risk of addiction.

69. These claims were misleading for a number of reasons. There is no reliable scientific evidence that high-risk or addicted patients can take opioids long-term without triggering addiction, even with enhanced monitoring and precautions. Nor is there reliable scientific evidence that patients without these red flags are necessarily free of addiction risk. And, there is no reliable scientific evidence that screening works to accurately predict risk or reduce rates of addiction. In fact, an Evidence Report by the Agency for Healthcare Research and Quality, which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent

monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[12]

70. The CDC Guideline confirms the falsity of the Opioid Manufacturers' claims about the utility of patient screening and management strategies in managing addiction risk. The CDC Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognized that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counseled that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

71. ***Fifth***, to encourage prescribers and patients to use chronic opioid therapy, the Opioid Manufacturers misdescribed the difficulty of withdrawing from opioids and claimed opioid withdrawal is simply managed. The Opioid Manufacturers routinely represented that while patients may become "physically" dependent on opioids, this dependence can be addressed by gradually tapering patients' doses to avoid the adverse effects of withdrawal. They failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—effects that also make it less likely that patients will be able to stop using the drugs.

72. In reality, withdrawal is prevalent in patients after more than a few weeks of therapy, and common symptoms of withdrawal include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, and pain. Some symptoms may

[12] *The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain*, Agency for Healthcare Res. & Quality (September 19, 2014).

persist for months, or even years, after a complete withdrawal from opioids, depending on how long opioids were used. Withdrawal symptoms trigger a feedback loop that drives patients to seek opioids, contributing to addiction.

73. ***Sixth***, the Opioid Manufacturers falsely represented that opioid doses can be increased without limit or greater risks. The Opioid Manufacturers claimed patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high," suggesting that patients would eventually reach a stable, effective dose. The Opioid Manufacturers also omitted warnings of increased adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

74. These claims are false and contrary to scientific evidence. Patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

75. The FDA has itself acknowledged that available data suggests a relationship between increased doses and the risk of adverse effects. Moreover, it is harder for patients to terminate use of higher-dose opioids without severe withdrawal effects, which contributes to a cycle of continued use, even when the drugs provide no pain relief and are causing harm—the signs of addiction. The CDC Guideline likewise concludes that the "[b]enefits of high-dose

opioids for chronic pain are not established" while there is "an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent." Accordingly, the CDC advises doctors to "avoid increasing dosage" above 90 mg MED per day.[13]

76. ***Seventh***, the Opioid Manufacturers deceptively omitted or minimized adverse effects of opioids and overstated the risks of alternative forms of pain treatment. Materials the Opioid Manufacturers produced, sponsored, or controlled omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or NSAIDs. None of these claims were corroborated by scientific evidence. In fact, several studies have shown that ibuprofen and acetaminophen taken together are better than opioids at relieving pain such as dental pain, low back pain, and moderate acute traumatic pain.[14]

77. The Opioid Manufacturers' promotional materials also routinely ignored other risks associated with opioids, such as hyperalgesia, a known serious risk associated with chronic opioid analgesic therapy, in which the patient becomes more sensitive to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (conditions that often accompany chronic pain symptoms).

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[13] Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, at 1503, NEJM (Apr. 21, 2016).

[14] Donald Teater, M.D., *Evidence for the Efficacy of Pain Medication*, National Safety Council (October 2014).

78. The Opioid Manufacturers' misrepresentations made healthcare providers more comfortable prescribing opioids to their patients and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because the Opioid Manufacturers aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Moreover, these misrepresentations allowed doctors to believe opioid addiction was really "pseudoaddiction" and a sign patients required more opioids.

79. The Opioid Manufacturers' false and misleading claims had the effect of shifting the balance of opioids' risks and purported benefits. The CDC reports that the quantity of opioids dispensed per capita tripled from 1999 to 2015. While opioid prescriptions exploded over the past two decades, the use of NSAIDs has dramatically declined. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[15]

80. The dramatic increase in opioid prescriptions to treat common chronic pain conditions caused a substantial rise in opioid overdose deaths and opioid addiction treatment admissions. Nationally, from 1999 through 2016, more than 350,000 people in the U.S. died from an overdose involving opioids. Over 200,000 of those deaths involved patients who were prescribed opioids to treat pain. In 2017, more than 70,000 people died of drug overdoses, approximately two-thirds of those deaths were linked to opioids. According to the CDC, opioids have created a "public health epidemic."

[15] Matthew Daubresse, et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States*, 2000-2010, 51(10) Med. Care 870 (2013).

J&J's Role in the Opioid Promotion Scheme

81. While the Opioid Manufacturer's deceptive marketing scheme caused devastating damage throughout the U.S., J&J profited handsomely from this unlawful scheme. Through its former subsidiaries, Tasmanian Alkaloids and Noramco, the Company supplied opium-based ingredients to a number of manufacturers for a range of drugs. Noramco and Tasmanian Alkaloids were the primary suppliers of the APIs for several opioid manufacturers. Eighty percent of Noramco's sales were with all seven of the top U.S. generic pharmaceutical manufacturers. Noramco and Tasmanian Alkaloids supplied opium-based ingredients—including Oxycodone, the API used in OxyContin, Percocet, and Roxicodone; Hydrocodone, the API used in Vicodin and Lortab; and Morphine, the API used in MS Contin and Embeda—to Teva, Endo, Purdue, Rhodes, Mallinckrodt, Actavis, Amneal, and KVK-Tech, among other manufacturers. Because Noramco and Tasmanian Alkaloids were the primary suppliers of the APIs for these opioid manufacturers, Janssen and J&J profited from the growth of both unbranded and branded opioids and was driven to develop the market as much as possible.

82. In 1997, after seeing the success that Purdue had in marketing OxyContin for chronic noncancer pain, J&J, through Janssen, relaunched its fentanyl-based DURAGESIC patch for the chronic noncancer market as well. J&J spent millions of dollars to promote DURAGESIC and its other branded opioids, NUCYNTA and NUCYNTA ER, and destigmatize and normalize the long-term use of opioids for chronic nonmalignant pain. Using multipronged marketing strategies that targeted physicians, other prescribers, and the general public through websites, print advertisements, and educational materials and events, the Company promoted both its own products and opioids in general as safe, effective, and appropriate for the long-term treatment of routine pain conditions. To create the appearance of objectivity, J&J obscured its involvement in certain of its marketing activities by collaborating with and funding various "front groups," which

wrote and disseminated favorable education materials and opioid treatment guidelines supporting opioid therapy for chronic pain.

83. A key component of the Company's marketing campaign was its sales representatives. The Company, through Janssen, aggressively targeted physicians and other high-volume prescribers by having its sales representatives visit these medical professionals to deliver favorable sales messages and educational materials supporting opioid therapy for chronic pain. J&J sales representatives falsely told prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work.

84. These sales representatives also falsely portrayed the Company's products as safer than other opioids. In particular, J&J sales representatives told prescribers that NUCYNTA and NUCYNTA ER were "unlike traditional opioids" and had "non-opioid" properties, implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to NUCYNTA and NUCYNTA ER. In truth, however, as set out in NUCYNTA's FDA mandated label, NUCYNTA "contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit." In addition, J&J sales representatives assured prescribers that NUCYNTA's unique properties eliminated the risk of addiction associated with the drug. In particular, the Company's sales representatives told prescribers that J&J's drugs were "steady state," implying that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.

85. The Company trained its sales representatives to perpetuate these falsehoods. A June 2009 NUCYNTA Training module warned Janssen's sales force that physicians are reluctant to prescribe controlled substances like NUCYNTA, but falsely assured this reluctance is

unfounded because "the risks ... are much smaller than commonly believed." The Company also trained its sales representatives to downplay the risk and impact of addiction by falsely representing that withdrawal from opioids was not an issue. A Janssen PowerPoint presentation used for training its sales representatives titled "Selling Nucynta ER" indicates that the "low incidence of withdrawal symptoms" is a "core message" for its sales force. This false message was repeated in numerous Janssen training materials between 2009 and 2011.[16]

86. The Company, through Janssen, also published misleading content online promoting the use of opioids generally. For example, Janssen's website for DURAGESIC included a section addressing "Your Right to Pain Relief" and a hypothetical patient's fear that "I'm afraid I'll become a drug addict." The website's response: "[a]ddiction is relatively rare when patients take opioids appropriately." Janssen also published a patient guide titled "Patient Booklet Answers to Your Questions – Duragesic," which reiterated that "[a]ddiction is relatively rare when patients take opioids appropriately."

87. The unbranded J&J website, PrescribeResponsibly.com, contained similar misrepresentations about opioids. This website stated that concerns about opioid addiction were "overestimated" and that "true addiction occurs only in a small percentage of patients." The

[16] The studies supporting this claim did not describe withdrawal symptoms in patients taking NUCYNTA ER beyond ninety days or at high doses and would therefore not be representative of withdrawal symptoms in the chronic pain population. Patients on opioid therapy long-term and at high doses will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Janssen relied upon a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use, when Janssen knew or should have known that these symptoms peak earlier than that for most patients. Relying on data after that initial window painted a misleading picture of the likelihood and severity of withdrawal associated with chronic opioid therapy. Janssen also knew or should have known that the patients involved in the study were not on the drug long enough to develop rates of withdrawal symptoms comparable to rates of withdrawal suffered by patients who use opioids for chronic pain—the use for which Janssen promoted NUCYNTA ER.

website also promoted the Company's messaging that the solution to "pseudoaddiction" was to prescribe more opioids.

88. To avoid regulatory constraints and give its efforts an appearance of independence and objectivity, J&J obscured its involvement in certain of its marketing activities by collaborating with patient advocacy organizations, such as the American Pain Foundation ("APF"), American Academy of Pain Medicine ("AAPM"), and American Society for Pain Management Nursing ("ASPMN"), to release misleading information about opioids. J&J provided funding to these groups and exercised significant influence over the educational programs and written materials they disseminated.

89. For instance, through Janssen, the Company sponsored and worked with the AAPM and the American Geriatrics Society ("AGS") to create a patient education guide titled "Finding Relief: Pain Management for Older Adults (2009)." The guide is rife with deceptive content about opioids. Among other misrepresentations, the guide claimed that long-term opioid use improves functioning. Using a myth/fact structure, the guide stated as "a fact" that "opioids may make it *easier* for people to live normally." The guide listed expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and stated that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

90. The guide also downplayed the addictive nature of opioids and suggested that as long as a prescription is given, opioid abuse was not an issue. Using the same fact/myth structure, the guide described the claim that opioids are addictive as a "myth," and asserted as "fact" that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain."

91. Additionally, the guide misrepresented that increased doses of opioids posed no significant additional risks, listing dose limitations as "disadvantages" of other pain medicines but omitting any discussion of risks of increased doses from opioids. The guide falsely claimed that it is a "myth" that "opioid doses have to get bigger over time."

92. In conjunction with the APF, AAPM, and ASPMN, Janssen also sponsored, developed, and approved misleading content about opioids on the website "Let's Talk Pain." Featuring an interview claiming that opioids allowed a patient to "continue to function," this website misrepresented that the use of opioids for the treatment of chronic pain would lead patients to regain functionality. The website also downplayed the risk of addiction from opioids, stating that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding about addiction." Let's Talk Pain also perpetuated the concept of pseudoaddiction, associating patient behaviors such as "drug seeking," "clock watching," and "even illicit drug use or deception" with undertreated pain which could be resolved with "effective pain management."

93. J&J also engaged in other promotional projects with and through APF. For example, J&J provided grants to APF to distribute the publication *Exit Wounds* to veterans. *Exit Wounds* deceptively portrayed the risks, benefits, and superiority of opioids for the treatment of chronic pain. The publication taught that opioid medications "*increase* your level of functioning" and omitted warnings of the risk of interactions between opioids and benzodiazepines,[17] which would increase fatality risk.

[17] Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.

94. The Company also used medical education events, including speakers bureau sessions and continuing medical education ("CME") opportunities as promotional endeavors to increase the market for opioids through misleading messaging. For instance, J&J created and funded the National Pain Education Council ("NPEC"), whose purpose was to provide CME related to pain and opioids to primary care physicians, pain specialists, oncologists, residents, nurses, and pharmacists. In the Company's 2003 Business Plan Summary for DURAGESIC, J&J described NPEC as serving "to benefit not only DURAGESIC but also all future Janssen pain products." CME materials for the Company's NPEC program disseminated false and misleading statements regarding opioids and pain management.

95. J&J, through Janssen, also contracted with AGS to produce a CME promoting the 2009 guidelines for the "Pharmacological Management of Persistent Pain in Older Persons." These guidelines falsely claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." The study supporting this assertion does not analyze addiction rates by age and addiction remains a significant risk for elderly patients. Janssen was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.

96. The Company was repeatedly notified that its opioid marketing, in its multitude of forms, was false, deceptive, and misleading. In 1998, the FDA found three different convention posters J&J used to promote DURAGESIC to contain marketing messages that were "false and misleading" for numerous reasons, including using misleading comparative efficacy claims without substantial evidence, taking data out of context to deliver misleadingly incomplete

impressions, promoting unapproved uses, emphasizing the "chronic pain" indications without the limitations and restrictions, and deceptively minimizing risks and safety issues.

97. In 2001, J&J's own hired scientific advisory board advised the Company that many of the primary marketing messages it used to promote opioids generally, and DURAGESIC specifically, were misleading and should not be disseminated. In particular, the Company's scientific advisory board advised J&J not to market opioids, including fentanyl-based DURAGESIC, using messages related to abuse or with claims about supposedly low abuse potential. The scientific advisory board noted that no data existed that could support these claims, that the data the Company pointed to (Drug Abuse Warning Network ("DAWN") data) was incapable of supporting these claims, that aggressively marketing OxyContin on this same basis was what had gotten Purdue "in trouble," that minimizing the risk of abuse of DURAGESIC was "dangerous" due to its lethal nature, and that an increase of DURAGESIC sales would cause an increase in abuse of the drug. The scientific advisory board warned the Company: "Do not include the abuse message. Do not sell opioids on the abuse issue."

98. Substantiating the advice of J&J's scientific advisors, in 2004, the FDA sent the Company a letter warning that a professional file card that J&J used to promote DURAGESIC contained "false or misleading claims about the abuse potential and other risks of [Duragesic], and include[d] unsubstantiated effectiveness claims for Duragesic." The FDA found that the DURAGESIC file card misbranded the drug by "suggesting that Duragesic has a lower potential for abuse compared to other opioid products," and "the file card could encourage the unsafe use of the drug, potentially resulting in serious or life-threatening hypoventilation." The FDA noted that J&J's suggestion that DURAGESIC was "less abused than other opioid drugs" was "false or misleading" because: (i) the FDA was "not aware of substantial evidence or substantial clinical

experience to support this comparative claim"; and (ii) "DAWN is not a clinical database" and "DAWN data cannot provide the basis for a valid comparison" among opioid products. The FDA concluded that the Company's DURAGESIC file card made "false or misleading safety claims and unsubstantiated effectiveness claims for Duragesic" and "thus misbrand[ed] Duragesic in violation of the Act (21 U.S.C. § 352(a))." The FDA advised J&J to "immediately cease the dissemination of promotional materials for Duragesic the same as or similar to those described" in the 2004 letter. The FDA further cautioned that the "violations discussed" in the letter did not "necessarily constitute an exhaustive list" and warned that it was J&J's responsibility to "ensure that [its] promotional materials for Duragesic comply with each applicable requirement of the Act and FDA implementing regulations."

99. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of DURAGESIC and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been "'examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch'" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs. Despite these warnings, J&J's deceptive marketing and sales of opioids continued.

J&J'S UNLAWFUL CONDUCT HAS SUBJECTED IT TO NUMEROUS LAWSUITS AND GOVERNMENTAL INVESTIGATIONS

100. The Company's deceptive marketing and promotion of opioids has subject J&J to numerous lawsuits and regulatory investigations. Since 2014, J&J and Janssen have been named as defendants in more than 2,500 lawsuits brought by various state and local governments related

to the marketing of opioids. Additionally, over 2,200 federal cases have been coordinated in a MDL pending in the U.S. District Court for the Northern District of Ohio.

101. The Company and Janssen have also received subpoenas or requests for information related to its opioid marketing practices from at least thirteen state attorneys general. In September 2017, attorneys general from a coalition of states who are investigating the distribution of prescription opioid pain medication sent the Company requests for documents and information. J&J and Janssen also received requests for information from the ranking minority member of the United States Senate Committee on Homeland Security and Governmental Affairs regarding the sales, marketing, and educational strategies related to the promotion of opioid use.

102. On June 18, 2018, a New York state court rejected motions to dismiss brought by J&J and other defendants, finding sufficient factual allegations to support causes of action for violations of New York's consumer fraud and false advertising laws, as well as public nuisance, negligence, fraud and other claims. In doing so, the New York court stated:

> The plaintiffs allege the manufacturer defendants employed assiduously crafted, multi-pronged marketing strategies that targeted the general public through websites, print advertisements, and educational materials and publications as part of their respective campaigns to change the perception of the risks associated with prescription opioids and to de-stigmatize and normalize the long-term use of opioids for chronic nonmalignant pain. According to the complaint, to perpetuate an increase in the amount and dosage of opioid prescriptions written for patients, and to optimize the market share for their respective products, the manufacturer defendants also aggressively targeted physicians and other prescribers, essential conduits in the sale of prescription opioids to the public, by having their sales representatives "detail" prescribers in face-to-face meetings, by inviting prescribers to attend informational programs, by hiring "product loyalists" to serve as paid speakers for such programs, and by using data mining to track opioid prescriptions and reward prolific prescribers of their products. Other alleged marketing strategies designed to affect physicians' prescribing practices included advertising in print journals and online, sponsoring continuing medical education courses, and hiring so-called "key opinion leaders" (KOLs) to act as consultants and serve as lecturers.

103. Judge Jerry Garguilo also noted that the plaintiffs alleged that J&J and the other manufacturing defendants funded fake front groups and spread other false information for the purpose of increasing sales of opioids, stating:

> The plaintiffs further allege that the manufacturer defendants' marketing campaigns included funding so-called "front groups," such as the American Pain Foundation and the American Academy of Pain Medicine, which wrote and disseminated favorable educational materials, published "scientific literature" without scientific bases, and created opioid treatment guidelines supporting opioid therapy for chronic pain. According to the complaint, in addition to providing those groups with substantial funding, the manufacturer defendants exercised significant influence over the educational programs and written materials, such as journal articles and treatment guidelines, regarding opioids presented by front groups and KOLs. Moreover, the plaintiffs allege that the manufacturer defendants sponsored websites created by front groups and accessible by the public that promoted prescription opioids as a means for improving patients' normal daily functions and quality of life.

104. On these allegations, the New York state court held that the plaintiffs "sufficiently allege[d] materially deceptive acts and practices by the manufacturer defendants that undermined consumers' ability to assess the benefits and dangers of prescription opioids and to make informed decisions as to the efficacy and safety of opioid therapy for chronic pain."

105. In November 2018, the New Jersey Attorney General filed a complaint against the Company in New Jersey state court accusing it of excessively distributing opioids in that state and of pushing opiates with marketing schemes premised on misleading statements about their risks and benefits. According to the complaint, Janssen deceptively marketed NUCYNTA pain relievers as safer and milder than other prescription opioids by claiming that NUCYNTA products were "unlike traditional opioids" and possessed "non-opioid" properties. The complaint alleges that "[t]his doublespeak ... masked the reality that Nucynta and Nucynta ER are not milder and are not less addictive" than other opioids categorized under Schedule II of the Controlled Substances Act.

106. On April 2, 2019, the Honorable Declan P. Mansfield denied the Company's motion to dismiss another lawsuit, filed in Florida state court, accusing J&J and others of misleading doctors into overprescribing opioids. In that lawsuit, Florida Attorney General Ashley Moody alleged that J&J conspired with other opioid distributors to sell and ship "ever-increasing quantities" of opioids into Florida, while using misleading marketing to convince doctors and their patients that opioids could be safely prescribed for chronic pain. According to the complaint, the companies knew or should have known there was no legitimate scientific basis for their claims to doctors and patients, yet they continued deceptively marketing and selling the drugs.

107. On August 26, 2019, the Honorable Thad Balkman ordered J&J to pay the state of Oklahoma $465 million after finding that J&J had intentionally downplayed the dangers and oversold the benefits of opioids. Judge Balkman found that J&J promulgated "false, misleading, and dangerous marketing campaigns" that "caused exponentially increasing rates of addiction, overdose deaths" and babies born exposed to opioids. On these findings, Judge Balkman ruled that J&J perpetuated a "public nuisance," substantially contributing to an ongoing public health crisis that could take decades to abate. In his order, Judge Balkman detailed J&J's deceptive conduct, stating that "[t]he greater weight of the evidence shows that Defendants did, in fact, engage in such false and misleading marketing" and specifically that:

> Among other things, they sent sales representatives into Oklahoma doctors' offices to deliver misleading messages, they disseminated misleading pamphlets, coupons, and other printed materials for patients and doctors, and they misleadingly advertised their drugs over the internet-all of which occurred here in Oklahoma. But Defendants also pervasively promoted the use of opioids generally. This "unbranded" marketing included things like print materials that misleadingly touted the safety and efficacy of opioids as a class of pain medication, as well as online materials that promoted opioids generally. Defendants used and viewed medical education events (including Speakers Bureau sessions and CME opportunities) as promotional endeavors that Defendants leveraged to increase the market for opioids through misleading messaging.

* * *

> ***According to Defendants' own internal training documents,*** Defendants concede that "False and Misleading" promotion includes at least the following types of conduct: ***Broadening of product indication;*** Data taken out of context; Minimization of safety issues; Omission of material information; Comparative efficacy or safety claims without substantial evidence; and Overstatements of efficacy or safety. … The greater weight of the evidence demonstrated that Defendants engaged in promotional activities that violated each one of these rules.

108. On September 4, 2019, the Honorable Dan Aaron Polster denied J&J and Janssen's motion for summary judgment in the MDL, finding that plaintiffs had alleged facts sufficient to support a RICO (Racketeer Influenced and Corrupt Organizations Act) claim against J&J and Janssen for participating in a criminal enterprise to pay kickbacks to doctors and disseminate false and misleading statements to promote opioid prescriptions and sales. Judge Polster found "Plaintiffs presented evidence sufficient to support a finding that each Manufacturer, including Janssen, engaged in misleading marketing activities that resulted in a substantial increase in the supply of prescription opioids and proximately caused harm to Plaintiffs." In doing so, Judge Polster noted that (i) "Plaintiffs point to evidence that suggests … Janssen contributed substantial sums of money to third parties who published misleading statements about prescription opioid use"; (ii) "Plaintiffs present evidence that, as part of its unbranded marketing efforts, Janssen funded third-party speech. Construing this evidence in the light most favorable to Plaintiffs, a jury could reasonably conclude these third-party statements constituted commercial speech that contained false and misleading statements regarding the risks and benefits of prescription opioid use, and that Janssen supported that speech for its own commercial benefit"; and (iii) "[E]ach Manufacturer, including Janssen, failed to maintain effective controls against diversion [of opioids to the black market]."

109. In mid-October 2019, media outlets reported that the Company had reached an agreement in principle with four attorneys general pursuant to which it would pay approximately ***$4 billion*** to settle the lawsuits in the U.S. accusing J&J of fueling the opioid epidemic.

110. On October 28, 2019, the Company reported that it had received in August a grand jury subpoena from the U.S. Attorney's Office for the Eastern District of New York related to its opioid medication policies. According to J&J's Quarterly Report on Form 10-Q filed with the SEC that day, the investigation relates to monitoring and reporting programs by manufacturers and distributors of opioids under the Controlled Substances Act.

DAMAGES TO J&J

111. The Individual Defendants' participation in the wrongdoing detailed above and failure to remedy the Company's improper business practices has exposed J&J to billions of dollars in liability for individual and class action lawsuits. J&J and Janssen have been named as defendants in thousands of lawsuits brought by various state and local governments related to their deceptive marketing of opioids. As the Company admitted in its Quarterly Report on Form 10-Q filed with the SEC on October 28, 2019, "[a]n adverse judgment in any of these lawsuits could result in the imposition of large monetary penalties and significant damages including, punitive damages, cost of abatement, substantial fines, equitable remedies and other sanctions."

112. Further, the Company has already been hit with hundreds of millions of dollars in judgments on claims that it intentionally downplayed the dangers and oversold the benefits of opioids. On August 26, 2019, the Honorable Thad Balkman ordered J&J to pay the state of Oklahoma $465 million after finding that the Company promulgated false, misleading, and dangerous marketing campaigns that caused exponentially increasing rates of addiction, overdose deaths, and babies born exposed to opioids. Two months later, on October 1, 2019, the Company announced that it had agreed to pay $20.4 million to resolve similar lawsuits in two Ohio counties.

113. The Individual Defendants' unwillingness to halt J&J's deceptive marketing and promotion of opioids also damaged the Company's reputation. In addition to price and product quality, J&J's current and potential customers consider a company's trustworthiness and ability to

truthfully market its products. Customers are less likely to do business with companies that knowingly permit and/or encourage unscrupulous behavior. As a September 11, 2019 *Forbes* article titled "J&J Shares Recover Amid $571 Million Fine, But Its Reputation May Never Recover," reported: "The Dow may care little for corporate ethics, but let's not forget that J&J's crown jewels are its line of baby care, first aid products, and household remedies, and unlike Wall Street, mothers don't as easily forgive or forget." An October 14, 2019 PRWeek.com article similarly pointed out the reputational damage the Company has suffered as a result of its involvement in the opioid crisis, stating: "Johnson & Johnson's public reputation is nearly at rock bottom of a new global ranking of the pharma industry." The article quoted Alva, a reputation intelligence company, as stating: "So far, we have seen clear evidence that J&J's reputation has been negatively affected by the issues it is facing. The key risk beyond the lawsuits and settlement costs is clearly the erosion of the company's brand promise."

114. Further, as a direct and proximate result of the Individual Defendants' actions, J&J has expended, and will continue to expend, significant sums of money. Such expenditures include, but are not limited to:

(a) costs incurred in defending and paying any potential settlement or adverse judgment in the thousands of lawsuits stemming from the Company's deceptive marketing and promotion of opioids;

(b) costs incurred from complying with the governmental investigations resulting from the improper practices detailed above; and

(c) costs incurred in connection with compensation and benefits paid to the Individual Defendants who have breached their duties to J&J.

DERIVATIVE AND DEMAND ALLEGATIONS

115. Plaintiff brings this action derivatively in the right and for the benefit of J&J to redress injuries suffered, and to be suffered, by J&J as a direct result of breaches of fiduciary duty and unjust enrichment, as well as the aiding and abetting thereof, by the Individual Defendants. J&J is named as a nominal defendant solely in a derivative capacity. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

116. Plaintiff will adequately and fairly represent the interests of J&J in enforcing and prosecuting its rights.

117. Plaintiff was a stockholder of J&J at the time of the wrongdoing complained of, has continuously been a stockholder since that time, and is a current J&J stockholder.

Demand Requirement Under Section 14A:3-6.3 of the New Jersey Revised Statutes

118. Section 14A:3-6.3 New Jersey Revised Statutes provides that a shareholder may commence a derivative proceeding after: "(1) a written demand has been made upon the corporation to take suitable action; and (2) 90 days have expired from the date the demand was made unless the shareholder has earlier been notified that the demand has been rejected by the corporation or unless irreparable injury to the corporation would result by waiting for the expiration of the 90-day period."

119. Here, as demonstrated below, plaintiff has alleged with particularity that: (i) he made a demand on the J&J Board to take action; and (ii) the Board ignored that demand for at least ninety days. Nothing more is required.

Plaintiff's Demand

120. In accordance with New Jersey law, on April 18, 2019, plaintiff sent the Demand to the Board to investigate, address, remedy, and commence proceedings against certain of the Company's current and former officers and directors for mismanagement and breaches of fiduciary

duties.[18] Plaintiff urged the Board to commence these legal proceedings as expeditiously as possible, and to secure tolling agreements from all potential defendants. To date, the Board has not substantively responded to the Demand and, upon information and belief, refused to take any action demanded.

121. Plaintiff received a response letter from Sidley Austin on behalf of the Company on May 3, 2019.[19] The Company's brief letter stated that Lowenstein Sandler was investigating the "underlying matters regarding the Company's opioid products that are addressed in [the Demand]." Although the Company's letter disclosed that Douglas Eakeley from Lowenstein Sandler was leading the investigation, it did not state who at J&J Mr. Eakeley was reporting to, nor whether the Board had established a committee to oversee the investigation. With respect to details of the investigation, the letter merely provided that the investigation was "underway and is currently in the fact-gathering stage." Notably, the Company's letter did not delineate the scope of the investigation, nor the anticipated duration of the investigation. Neither did the Company's letter address whether the Board had secured tolling agreements from potential defendants, as plaintiff had explicitly demanded in the Demand.

122. Over six months later, after receiving scant information regarding the scope and timing of the investigation, on October 21, 2019, plaintiff's counsel wrote to Company counsel inquiring into the status of the investigation into his Demand.[20] Plaintiff noted that J&J had recently agreed to pay $20.4 million to resolve claims by two Ohio counties that the Company fueled the opioid crisis in the U.S. Plaintiff also pointed out that reports indicated that J&J was

[18] A true and correct copy of the Demand is attached hereto as Exhibit A.

[19] A true and correct copy of the May 3, 2019 letter is attached hereto as Exhibit B.

[20] A true and correct copy of the October 21, 2019 letter is attached hereto as Exhibit C.

proposing to pay $4 billion to resolve portions of the opioid MDL. Plaintiff stressed the importance of having independent individuals overseeing the Company's entrance into these agreements, and urged J&J to act expeditiously to hold those responsible for damaging the Company accountable. Plaintiff also requested the names of the Board members charged with overseeing the Company's opioid litigation efforts.

123. Sidley Austin responded with a one-page letter dated November 1, 2019.[21] In the letter, counsel did little more than reiterate that Mr. Eakeley of Lowenstein Sandler was leading the investigation into J&J's opioid marketing practices. Counsel did not address plaintiff's request for the names of the Board members charged with overseeing the Company's opioid litigation efforts. Nor did counsel mention plaintiff's previous demand that J&J enter into tolling agreements with all potential defendants.

124. On November 11, 2019, plaintiff's counsel sent Sidley Austin another letter.[22] In the letter, plaintiff's counsel expressed concern over the Board's delay in investigating plaintiff's Demand and requested written confirmation that the Company had entered into tolling agreements with the potentially culpable fiduciaries. Plaintiff's counsel also sought confirmation that the Company had not released any claims covered by the Demand. Finally, plaintiff's counsel noted that under New Jersey law, he was entitled to take action given the Board's delay in responding.

125. In a brief letter dated December 6, 2019, Sidley Austin responded.[23] Counsel reiterated that it remained uncertain when the investigation would be complete. Further, despite plaintiff having first demanded the Company secure tolling agreements against the culpable

[21] A true and correct copy of the November 1, 2019 letter is attached hereto as Exhibit D.

[22] A true and correct copy of the November 11, 2019 letter is attached hereto as Exhibit E.

[23] A true and correct copy of the December 6, 2019 letter is attached hereto as Exhibit F.

fiduciaries nearly eight months prior, counsel stated that J&J was only now considering the request. Counsel did not address plaintiff's request for confirmation that the Company had not released any claims covered by the Demand.

126. Over seven months—nearly three times the statutory period—have now passed since plaintiff sent the Demand, yet the Board has not provided a substantive response despite the obligation under section 14A:3-6.3 to respond to the Demand within ninety days.[24] The Board's response to the Demand is contrary to New Jersey law, and this delay demonstrates that the Board is acting in bad faith in considering the Demand. Accordingly, no further delay is warranted or appropriate here, and thus, in accordance with New Jersey law, plaintiff is entitled to pursue this action.

127. Plaintiff has not made any demand on the other stockholders of J&J to institute this action since such demand would be a futile and useless act for at least the following reasons:

(a) J&J is a publicly held company with over 2.6 billion shares outstanding and thousands of stockholders as of October 22, 2019;

(b) making demand on such a number of stockholders would be impossible for plaintiff who has no way of finding out the names, addresses, or phone numbers of stockholders; and

(c) making demand on all stockholders would force plaintiff to incur excessive expenses, assuming all stockholders could be individually identified.

[24] Under the statutory requirements, the required ninety-day period expired on July 17, 2019.

COUNT I

Against the Individual Defendants for Breach of Fiduciary Duty

128. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

129. The Individual Defendants owed and owe J&J fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed and owe J&J the highest obligation of good faith, fair dealing, loyalty, and due care.

130. The Individual Defendants and each of them, violated and breached their fiduciary duties of candor, good faith, and loyalty. More specifically, the Individual Defendants violated their duty of good faith by creating a culture of lawlessness within J&J, and/or consciously failing to prevent the Company from engaging in the unlawful acts complained of herein.

131. The Officer Defendants either knew, were reckless, or were grossly negligent in disregarding the illegal activity of such substantial magnitude and duration. The Officer Defendants knowingly, recklessly, or with gross negligence caused or allowed the Company to engage in an illicit marketing scheme to expand the market and increase demand for opioids. The deceptive marketing scheme worked—opening the floodgates of opioid use and abuse. By failing to prevent the Company from engaging in this deceptive conduct despite repeated warnings, the Officer Defendants effectively condoned this unlawful activity. Accordingly, the Officer Defendants breached their duty of care and loyalty to the Company.

132. The Director Defendants, as directors of the Company, owed J&J the highest duty of loyalty. These defendants breached their duty of loyalty by knowingly or recklessly causing or allowing the Company to engage in an illicit marketing scheme to expand the market for opioids and unlawfully increase its revenues from opioids. By failing to prevent the Company from engaging in this deceptive conduct despite repeated warnings, the Director Defendants effectively

condoned this unlawful activity. Accordingly, these defendants breached their duty of loyalty to the Company.

133. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, J&J has sustained significant damages, as alleged herein. As a result of the misconduct alleged herein, these defendants are liable to the Company.

134. Plaintiff, on behalf of J&J, has no adequate remedy at law.

COUNT II

Against the Individual Defendants for Unjust Enrichment

135. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

136. By their wrongful acts and omissions, the Individual Defendants were unjustly enriched at the expense of and to the detriment of J&J. The Individual Defendants were unjustly enriched as a result of the compensation and director remuneration they received while breaching fiduciary duties owed to J&J.

137. Plaintiff, as a stockholder and representative of J&J, seeks restitution from these defendants, and each of them, and seeks an order of this Court disgorging all profits, benefits, and other compensation obtained by these defendants, and each of them, from their wrongful conduct and fiduciary breaches.

138. Plaintiff, on behalf of J&J, has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, on behalf of J&J, demands judgment as follows:

A. Against all of the defendants and in favor of the Company for the amount of damages sustained by the Company as a result of the defendants' breaches of fiduciary duties and unjust enrichment;

B. Directing J&J to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect J&J and its stockholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for stockholder vote, resolutions for amendments to the Company's Bylaws or Articles of Incorporation and taking such other action as may be necessary to place before stockholders for a vote of the following corporate governance policies:

1. a proposal to strengthen the Company's controls over marketing and sales of opioids;

2. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater stockholder input into the policies and guidelines of the Board; and

3. a provision to permit the stockholders of J&J to nominate at least three candidates for election to the Board;

C. Extraordinary equitable and/or injunctive relief as permitted by law, equity, and state statutory provisions sued hereunder, including attaching, impounding, imposing a constructive trust on, or otherwise restricting the proceeds of defendants' trading activities or their other assets so as to assure that plaintiff on behalf of J&J has an effective remedy;

D. Awarding to J&J restitution from defendants, and each of them, and ordering disgorgement of all profits, benefits, and other compensation obtained by the defendants;

E. Awarding to plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

F. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: December 12, 2019

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s/ Serina M. Vash

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**pro hac vice motions to be filed*

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